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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,551	01/08/2001	Casey D. Morrow	UAI-004CPDV2CN	6750

959 7590 11/18/2002  
LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER  
WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 11/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/756,551

Applicant(s)  
Morrow et al.

Examiner  
Joseph T. Weitach

Art Unit  
1632



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Aug 26, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 35-39 and 45-63 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 35-39 and 45-63 are subject to restriction and/or election requirement

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

This application is a continuation of 09/376,184, filed August 17, 1999, now abandoned, which is a continuation of 08/987,867, filed December 9, 1997, now patent number 6,063,384, which is a continuation of 08/389,459, filed February 15, 1995, now patent number 5,817,512, which is a continuation of 08/087,009, filed July 1, 1993, now abandoned.

Applicants amendment filed August 26, 2002, paper number 10, has been received and entered. Claims 1-34 and 40-44 have been canceled. Claims 35, 38, 29 and 45 have been amended. Claims 46-63 have been added. Claims 35-39 and 45-63 are pending and currently under examination.

### ***Election/Restriction***

Applicant's election without traverse of Group IV, drawn to a method of stimulating the immune response system of a subject, in Paper No. 11 is acknowledged. However, the amendment filed on August 26, 2002 canceling the claims drawn to the elected invention and presenting only claims drawn to a non-elected invention is non-responsive (MPEP § 821.03). The pending claims are not readable on the elected invention because they have been amended from expressing an immunogenic protein to expressing other types of proteins. Previously, the claims were drawn to expressing and stimulating an immune response to immunogenic proteins or fragments thereof, in particular dependent claims set forth several viral proteins of HIV-1.

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Presently, the claims have been amended to encompass general methods of delivery and dependent claims are now drawn to expressing biologically active proteins such as interleukin, cytokines and other factors and biologically active molecules including antisense sequences and ribozymes. The presently pending claims are drawn to gene therapy methodology encompassing the expression of completely different proteins than previously encompassed by the previous claims, requiring a different and separate search. Stimulating an immune response affectively only requires adequate expression of a given antigen, wherein the present claims encompass biologically active molecules with biological affects on the subject, requiring a separate search of each of the molecules in their respective and relative art, and further consideration of each of the effects upon delivery. Additionally, if the present claims were presented, they would be further restricted into methods directed to each of the different types of biologically active molecules expressed, *i.e.* cytokine, ribozyme, antisense.

If the previous claims and the presently pending claims were presented together they would be found to be unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The separate methods require different polynucleotide sequences, and the expression of the polynucleotides results in physiologically different effects in the subject. The search required for methods of generating an immune response by expressing an antigen is different than that required for gene therapy methods for delivering biologically active molecules.

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Because these inventions are distinct for the reasons given above have acquired a separate status in the art as shown by their different classification and divergent subject matter restriction for examination purposes as indicated is proper.

Since the above-mentioned amendment appears to be a bona fide attempt to reply, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS, whichever is longer, from the mailing date of this notice within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD UNDER 37 CFR 1.136(a) ARE AVAILABLE.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

*Deborah Crouch*  
DEBORAH CROUCH  
PRIMARY EXAMINER  
GROUP 1800/630

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach